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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,847	06/23/2003	Martin S. Linsell	P-089-US2	8088

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,847	LINSELL ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,28,33 and 37-40* is/are rejected.

7)☒ Claim(s) *29-32 and 34-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20030902*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The status of the parent application in the claim for priority inserted at page 1 of the specification should be updated.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the group recited at claim 28, page 9 of the preliminary amendment filed June 23, 2003, line 5. Note that page 10, line 9, of the specification recites a benzyloxy rather than a phenyloxy group.

3. Claim 28 is objected to because of the following informalities: At claim 28, page 8 of the preliminary amendment filed June 23, 2003, third-to-last line, the beginning bracket does not match the end parenthesis. Appropriate correction is required.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 27, 33, 37, 38, and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,620,781. Although the conflicting claims are not identical, they are not patentably distinct from each other. The compound recited in instant claim 27, part (c), differs from the compound claimed in claim 16 of the '781 patent in that the compound claimed in claim 16 of the '781 patent does not require that R^3 be OH, although claim 16 embraces the possibility that R^3 can be OH. See the definitions of R^3, $-OR^c$, and R^c in claim 6, upon which claim 16 depends. It would have been obvious to one of ordinary skill in the art to form compounds according to claim 16 of the '781 patent in which R^3 is OH because such compounds are generically embraced by the claim; because OH is the typical substituent which occurs at the R^3 position of vancomycin, of which the claimed compounds of the '781 patent are analogs; and because the resulting compound has only the anti-bacterial activity which would have been expected in view of the claims of the '781 patent.

6. Claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,620,781 in view of Bodor (U.S. Patent No. 4,983,586). The '781 patent does not claim combining its compounds with a hydroxypropyl-β-cyclodextrin carrier. Bodor teaches that aqueous parenteral solutions of drugs which are insoluble or only sparingly insoluble in water and/or which are unstable in water can be combined with hydroxypropyl-β-cyclodextrin. The drugs include antibacterials/antibiotics. See, e.g., the Abstract and column 14, line 62. It would have been obvious to one of ordinary skill in the art to include the hydroxypropyl-β-cyclodextrin of Bodor in the claimed compositions of the '781 patent because the hydroxypropyl-β-cyclodextrin is a known and useful species of

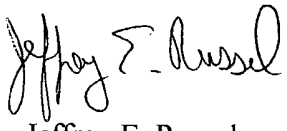
the cyclodextrin which is claimed in the '781 patent and because the hydroxypropyl-β-cyclodextrin would have been expected to improve the solubility and/or stability of claimed compounds of the '781 patent.

7. Claims 29-32 and 34-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 28 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, and the claim objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. These claims are not rejected on the basis of obviousness-type double patenting over the claims of U.S. Patent No. 6,620,781 because the claims of the '781 patent are too broad to suggest the particular compounds recited in these claims. The prior art of record does not teach or suggest these compounds for the reasons set forth during prosecution of the parent application.

U.S. Patent No. 6,770,621 is cited as art of interest, but does not raise any issues of obviousness-type double patenting with the instant claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

September 15, 2004